



Review

Exploring breast implant illness and its comorbid conditions: A systematic review & meta-analysis



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KEYWORDS Breast Augmentation; Breast Reconstruction;	Abstract Introduction: Despite growing interest, there is scarce literature that describes the comorbid conditions and presenting symptoms that can manifest with or potentially as breast implant illness (BII). This review aims to address this gap. Methods: A systematic search was conducted on September 24, 2024, using EMBASE, PubMed,
Breast Implantation; Breast Surgery; Breast Prostheses	Scopus, Web of Science, and Google Scholar. Inclusion criteria required the exploration of BII in relation to autoimmune disorders in peer-reviewed original research. Two investigators independently conducted the screening, extraction, and analysis.
	Results: Of the 1362 reports identified, 48 articles were selected for analysis. These studies were conducted globally and included 7045 patients with breast implants (bilateral or unilateral). Of these, 3444 patients (49%) presented with the constellations of symptoms often classified as "breast implant illness." 2425 patients (34%) reported complaints of arthralgia and/or myalgia, 1477 patients (21%) reported cognitive dysfunction such as brain fog and/or loss of concentration, and 1685 patients (24%) reported fatigue and/or malaise. Additionally, 409 patients (6%) had a diagnosed comorbid autoimmune condition, while 1005 (14%) had a history of former or active smoking. Significant associations were found between likelihood of reporting BII, history of malignancy, likelihood of undergoing explantation, and symptom improvement or complete resolution postexplantation.
	<i>Conclusion:</i> Among the patients that presented with one or more symptoms of BII, 51% had other explainable diagnoses or etiologies for their symptoms that precluded the diagnosis of

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BII. These findings highlight the need for more research into BII etiology, diagnosis, and management and improved patient education and follow-up protocols.

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Background

Breast implant illness (BII) is the constellation of symptoms related to breast implants, often including, but not limited to, brain fog, fatigue, joint pain, muscle pain, and hair loss.¹⁻²² There is no single established definition of BII and no strict diagnostic criteria, including no specific set of laboratory abnormalities.¹⁻²² Some symptoms of BII meet the diagnostic criteria of other autoimmune and somatic conditions and may be misdiagnosed as chronic fatigue syndrome, fibromyalgia, and undifferentiated connective tissue diseases.¹

The diagnosis is primarily based on the patients' subjective association of the symptoms with breast implantation.¹⁻²² The symptoms are often associated with the placement of silicone breast implants but can be seen in patients with other types of implants, such as saline.¹⁻²² BI remains controversial, due to the substantial evidence supporting the overall safety of implants.¹⁻²² Despite this, patients with BII have reported improvement or complete resolution of symptoms following implant removal.¹⁻²²

Since BII lacks an established definition and strict diagnostic criteria, patients typically self-diagnose.^{3,5,8,19,23,24} Some critics argue that BII is primarily a "social media phenomenon," suggesting that social media platforms generate or contribute to ongoing anxiety and self-diagnosis.^{3,5,8,19,23,24} Medical professionals often attribute BII symptoms to psychological disorders or deny its existence.^{3,5,8,19,23,24} This ongoing controversy and uncertainty regarding the etiology and diagnosis of BII underscores the paramount need for increased awareness and clarity through research that clearly documents the most prevalent presenting symptoms and comorbid conditions found in patients reporting BII.^{1-13,15-20,22,25}

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Research objectives

The objective of this systematic review was to identify the most common presenting complaints among women with breast implants and the most prevalent comorbid conditions found in women who present with the constellation of symptoms of BII. Additionally, the meta-analysis aimed to establish any correlations between the most prevalent comorbid conditions and the reporting of BII, with the goal of identifying potential risk factors or precipitating conditions.

Methods

Search strategy and database search

This systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.²⁶ A search of five databases consisting of Excerpta Medica Database (EMBASE), PubMed, Scopus, Web of Science, and Google Scholar was conducted on September 24, 2024. To optimize the retrieval of relevant articles, a search strategy was developed to use key terms in a string to ensure a cohesive search of the current literature related to BII, breast reconstruction or augmentation, common patient presentations often associated with breast implants such as mastodynia and anxiety, and breast implant explantation or removal. A tailored search string for each database was created using a combination of Medical Subject Headings (MeSH) and free text, when applicable. The details of the queries can be found in the appendix. For the Web of Science database specifically, only the first 200 results were considered to ensure the most relevant articles were included in this review. To reflect the recent growing interest in BII in recent years, articles published before 2018 were excluded. All identified articles were imported into Endnote software (Version 20.4.1) for reference management.

Study eligibility and selection process

The database search identified 1362 articles. After removing 312 duplicate records, screening of titles and abstracts eliminated 946 irrelevant records. Two independent reviewers (M.T. and S.H.) performed an eligibility assessment to identify studies meeting the inclusion criteria. The inclusion criteria specified peer-reviewed original research published after 2018 that focused on the patient's clinical experience with BII. Reasons for exclusion included duplicate or unretrievable articles, correspondence, review articles, educational materials (book chapters), non-peer-reviewed or retracted reports, articles lacking an English translation, pre-2018 publications, articles that were not patient-centered (not related to the patient's clinical experience), and articles describing autoimmune disorders unrelated to BII. An overview of the eligibility criteria is located within the appendix. Figure 1 demonstrates this process in accordance with the PRISMA guidelines.²⁶

Data collection

Study details and characteristics of comorbid conditions as well as initial patient presentations were systematically

extracted and organized using Microsoft Excel. Basic details extracted included the article type and journal. Details regarding the patients' experience of BII included the total number of patients with breast implants, the total number of patients with breast implants that reported the constellation of symptoms often grouped as BII, the types of breast implants used, the number of patients with each type of breast implant, the number of patients with each type of breast implant reporting these symptoms, the initial signs and symptoms patients presented with, any comorbid condition reported from a patient's medical history, as well as the number of patients who removed their implants, and if their symptoms improved or resolved postexplantation. This data was then analyzed, summarized, and synthesized to offer a comprehensive overview of the comorbid conditions and patient complaints observed in these studies.

Risk of bias assessment

To assess bias in the selected papers, two researchers conducted an independent assessment using the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Case Reports²⁷ (17 articles),^{4,24,28-42} JBI Critical Appraisal Checklist for Case Series⁴³ (two articles),^{44,45} and the Newcastle-Ottawa Scale (NOS)⁴⁶ for nonrandomized studies (27 articles).^{1-3,5,7,9-15,18-23,25,47-54} Two articles^{8,16} were focused on a cross-sectional study; therefore, the AXIS tool (Appraisal tool for Cross-Sectional Studies)⁵⁵ was used to assess risk of bias. Discrepancies in assessments between the first two authors were resolved by the third author independently. Upon completion of the bias evaluation, a chart and summary of both the JBI assessment for case reports and the NOS assessment for nonrandomized studies were created using Microsoft Excel and Microsoft Word.

Data analysis

The relationship between percentage of patients with a diagnosis of BII and percentage of comorbidities were initially modeled by linear regression, with study sample size as weights. The Spearman correlation test was also completed to show the relationship, without assuming a normal distribution and linear relationship between percentage of patients with BII and percentage of comorbidities. To avoid bias from extremely small studies, such as case reports and case series, a secondary sensitivity analysis was conducted, excluding studies with sample size < 20. The analysis was performed using R4.2.2 (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/.).

Results

Characteristics of included articles

Studies focusing on the patient's clinical experience with the constellations of symptoms often described as BII were selected for the systematic review. Seventeen articles^{4,24,28-42} were case reports, two were case series, ^{44,45} and 29 were



Figure 1 2020 PRISMA for this Systematic Review and Meta-Analysis.

nonrandomized studies, including 26 retrospective and/or prospective cohort studies, $^{1-3,5,7,9-15,18-23,25,47-50,52-54}$ one case control study, 51 and two cross-sectional studies. 8,16 The articles spanned 28 journals. Table 1 summarizes the key findings from the included articles.

Risk of bias

Table 2 shows a summary of the results of the included studies evaluated using the JBI Critical Appraisal Checklist

for Case Reports (17 articles).^{4,24,28-42} Table 3 shows a summary of the results of the included studies evaluated using the NOS for cohort studies (26 articles).^{1-3,5,7,9-15,18-23,25,47-50,52-54} The NOS for case control studies was used for one article⁵¹ Nagy et al., 2024, which was deemed minimal risk for bias and thus, was included in this review. The AXIS tool was used for Newby et al., 2021 and Magno-Padron et al., 2021. Both studies^{8,16} were deemed low risk for bias and were included in this systematic review. Additionally, the JBI Critical Appraisal

Table 1 Summary of All Include	ded Articles in this Systematic Review and Meta-Analysis.
Article	Key Study Findings
Alijotas-Reig et al. 2018 ⁴⁴	This series showed that foreign materials, particularly biomaterials used in esthetic, cosmetic, and plastic surgery, can induce foreign body immune-mediated reactions and sometimes yield or trigger the onset of systematic autoimmune disorders, some of which fulfill autoimmune/inflammatory syndrome induced by adjuvants (ASIA) criteria.
Asra et al. 2018 ²⁸	Silicone implant incompatibility syndrome is a mimic for metastases and should be considered as a differential diagnosis for interpretation in patients with silicone breast implants.
Singh et al. 2018 ⁵²	Breast augmentation is not a significant contributor to pulmonary disease requiring lung transplantation.
Khoo et al. 2019 ⁵⁰	Fibromyalgia and chronic fatigue syndrome are more common in patients with silicone implants than in controls with systemic sclerosis but not in controls with systemic lupus erythematosus.
Johansen et al. 2020 ³³	Recurrent pneumonia, chronic cough, and atypical chest pain are symptoms to take seriously and if the patient has silicone breast implants, they may be causing chronic inflammation and should always be investigated.
Lee et al. 2020 ²³	Microbiological and histological abnormalities in a significant number of patients have been identified, and a large proportion of patients have reported resolution or improvement of breast implant illness (BII) symptoms post explantation.
Marano et al. 2020 ²⁴	This case report investigated the ambiguity of the role of a patient's breast implant in their presentation, whose clinical picture improved dramatically after removal of their silicone breast implant.
Patel et al. 2020 ⁴⁰	This case report reported the successful treatment of BII in a patient with breast implants: the integration of complementary and alternative medicine in combination with breast implant removal.
Wee et al. 2020 ²¹	This study demonstrated a strong association of explantation and BII symptom improvement within the patient population studied.
Woźniak-Roszkowska et al. 2020 ⁵⁴	The assessment of symptoms and screening for autoimmune or autoinflammatory syndromes is a necessary part of the examination of every patient presenting after breast augmentation.
Chopra et al. 2021 ²⁹	Siliconoma should be added to the differential when evaluating fatigue not attributable to other medical conditions in patients with breast implants.
Colaris et al. 2021 ⁴⁷	An increased risk of cognitive failure in patients with silicone breast implants when compared to healthy controls could not be found.
de Paula & Santiago 2021	When treating patients with breast implants and systemic clinical manifestations and symptoms without other defined etiology, the possibility of ASIA should be considered in the differential diagnosis.
Katsnelson et al. 2021 ⁵	Implant removal with capsulectomy can be safely performed in patients with BII with a low complication and high patient satisfaction.
Magno-Padron et al. 2021 ⁸ Misère et al. 2021 ¹⁴	Nearly all patients in this study reported improvement of symptoms after breast implant removal. The adjusted prevalence of BII manifestations is not significantly higher in women with silicone breast implants than in women without implants, suggesting that results on BII are subject to selection bias.
Newby et al. 2021 ¹⁶	This study highlights the need for further investigation into the causes, risk factors, long- term effects, and potential interventions for women who experience BII.
Wee et al. 2021 ⁵³	This study demonstrates that patients presenting with BII with pulmonary complaints had significant improvement in pulmonary function after complete implant explantation.
Bird & Niessen 2022 ²⁵	This is the largest prospective cohort study on silicone breast implant explantation showing significant improvement of BII as well as improved breast satisfaction and overall quality of life.
Glicksman et al. 2022 ³	Patients who self-reported BII demonstrated a significant improvement in their symptoms after explantation and that this improvement persisted for at least 6 months, regardless of the type of capsulectomy performed.
Habib et al. 2022 ⁴⁵	This case series demonstrated three patient cases with BII who experienced resolution of symptoms after en-bloc resection.
Loftis et al. 2022 ³⁵	This case report emphasizes the need for a multidisciplinary approach in the diagnosis and management of patients with ASIA due to breast implants.
McCarthy et al. 2022 ³⁷ Metzinger et al. 2022 ¹²	Evidence suggests that biofilm infection with <i>C. acnes</i> may play a role in BII development. This study shows that implant removal with capsulectomy drastically improves BII symptoms.
	(continued on next page)

Table 1 (continued)	
Article	Key Study Findings
Miseré & van der Hulst 2022 ¹⁵	A relatively low prevalence of suggested BII exists among women undergoing explantation, and allergy and implant rupture may increase the likelihood of having BII.
Mustafá et al. 2022 ³⁸	Silicone migration is possible via cohesive silicone gel breast implant leakage and may causes local silicone toxicity and defects.
Spit et al. 2022 ²⁰	Most women with silicone breast implants who developed systemic symptoms experienced improvement after explantation, especially when removed within 10 years after implantation.
Van Assche et al. 2022 ⁴²	This case report highlights the possibility of a sensory ganglionopathy as the first symptom of Sjogren's syndrome in the setting of ASIA in a patient with silicone breast implants.
Bascone et al. 2023	In the setting of suspected or diagnosed BII, a reduced time to implant removal may decrease the risk of residual symptoms and improve overall patient satisfaction.
Glicksman et al. 2023 ²	Patients with BII had heightened symptoms and poorer baselines compared to control cohorts, and there was improvement seen postexplantation, highlighting a potential placebo effect and the need to reduce negative expectations.
Greenbaum et al. 2023 ⁴⁹	A significant reduction in hearing difficulties was observed following silicone implant removal.
Hernandez & Manuel 2023 ³²	It is necessary to identify risk factors for the development of autoimmune phenomena in patients with breast implants.
Messa & Messa 2023 ¹¹	This study presents an effective paradigm to manage implant removal through simultaneous explantation, capsulectomy, and mastopexy with acceptable clinical outcomes and a significant improvement in quality of life and breast esthetics.
Oliveira et al. 2023 ³⁹	This study aims to contribute to future research on ASIA by helping health providers with the diagnosis and to raise awareness about the consequences of breast implantation.
Serena et al. 2023 ¹⁸	This study highlights the extensive morbidity of BII. There is an opportunity to standardize treatment for this disease, demonstrating that there is significant reduction in disease severity after breast implant explanation and total capsulectomy.
Tanev et al. 2023 ⁴¹	The complaints of both described patients with silicone-induced ASIA improved significantly in response to immunosuppressive therapy despite the preservation of silicone breast implants.
Zhang et al. 2023 ²²	As the years of implant wearing increase, the proportion of subjective reasons decrease in implant removal cases and objective reasons increase among them.
Danino et al. 2024 ⁴⁸	This study highlights that silicone migration is not the sole cause of BII.
Girolami et al. 2024 ³¹	This is the first report of the co-occurrence of multicentric reticulohistiocytosis with ASIA, and this is relevant to broaden the spectrum of both rare diseases.
Kasielska-Trojan et al. 2024 ⁴	Dissatisfaction with the result of breast implantation can lead to somatization and the presence of real clinical symptoms, which should not be confused with the possible autoimmune reaction to silicone particles.
Lieffering et al. 2024 ⁷	Women who underwent explantation of breast implants had higher utilization of medical specialist care in the years before explantation compared to women who underwent breast implant replacement surgery and women without breast implants.
Littman et al. 2024 ³⁴	This case report highlights the importance of considering the possible health implications of breast implants from a rheumatological perspective.
Maitani et al. 2024 ³⁶	This case report adds more clinical evidence of adult-onset Still disease associated with silicone breast implants.
McCranie et al. 2024 ⁹	Transwomen exhibit a significant increase in breast well-being after breast augmentation, but some patients also experience a decreased well-being due to BII.
McGuire et al. 2024 ¹⁰	Explantation with or without capsulectomy provides symptom improvement in patients with systemic symptoms they associate with implants.
Miranda et al. 2024 ¹³	Capsulectomy and implant removal may not be curative in patients with BII, but symptom improvement can occur.
Nagy et al. 2024 ⁵¹	Mast cell counts in implant capsules in BII patients are increased and some patients appear to have unrecognized BII.
Spit et al. 2024 ¹⁹	Women with a high or moderate BII suspicion benefit significantly more from explantation than women with low suspicion.

Table 2 JBI Risk of Bias Assessment.									
Questions	Asra et al 2018 ²⁸	. Chopra et al. 2021 ²	de Paula & Santiago 2021 ³⁰	Girolami et al. 2024 ³¹	Hernandez & Manuel 2023 ³²	Johansen et al. 2020 ³³	Kasielska-Trojan et al. 2024 ⁴	Littman et al. 2024 ³⁴	Loftis et al. 2022 ³⁵
Were patients' demographic characteristics clearly described?	Y	٢	٢	Y	٨	٢	Y	٢	Y
Was the patient's history clearly described and presented as a timeline?	≻	≻	≻	~	~	~	~	~	≻
Was the current clinical condition of the patient on presentation clearly described?	≻	~	~	~	~	~	~	~	~
Were diagnostic tests or assessment methods and the results clearly described?	≻	≻	~	~	~	~	~	~	≻
Was the intervention(s) or treatment procedure(s) clearly described?	z	≻	≻	≻	~	×	×	≻	≻
Was the postintervention clinical condition clearly described?	z	≻	~	~	~	~	۲	≻	~
Were adverse events (harms) or unanticipated events identified and described?	≻	≻	≻	~	~	~	~	~	≻
Does the case report provide takeaway lessons?	≻	≻	≻	۲	~	×	×		~
Questions	Mã 20	iitani et al. 24 ³⁶	Marano et al. 2020 ²⁴	McCarthy et al. 2022 ³⁷	Mustafá et al. 2022 ³⁸	Oliveira et al. 2023 ³⁹	Patel et al. Ta 2020 ⁴⁰ 20	inev et al. Var)23 ⁴¹ et	ı Assche al. 2022 ⁴²
Were patients' demographic characteristic: clearly described?	s Y		×	٢	٢	Y	Y Y	Y	
Was the patient's history clearly described presented as a timeline?	and Y		~	~	~	≻	≻ ≻	≻	
Was the current clinical condition of the pa on presentation clearly described?	atient Y		~	~	~	≻	≻	~	
Were diagnostic tests or assessment methor and the results clearly described?	Y sbc		~	~	~	≻	≻	~	
Was the intervention(s) or treatment proce (s) clearly described?	edure Y		~	7	~	≻	≻	~	
Was the postintervention clinical condition clearly described?	~		~	~	~	≻	≻	~	
Were adverse events (harms) or unanticipa events identified and described?	ated Y		~	~	~	≻	≻	~	
Does the case report provide takeaway les	sons? Y		۲	٢	۲	۲	۲ ۲	Y	
Abbreviations: $N = No$, $Y = Yes$									

Table 3 Newcastle-O	ttawa Scale Risk of	Bias Assessment.						
Study	Selection				Comparability of cohorts	Outcome		
	Representative of the exposed cohort	Selection of external control	Ascertainment of exposure	Outcome of interest not present at the start of the study	Main factor (only main factor was considered in this review)	Assessment of outcomes	Sufficient follow- up time	Adequacy of follow-up
Bascone et al. 2023 ¹	*		*	*	NA		*	*
Bird & Niessen 2022 ²⁵	*	*	*	*	*		*	*
Colaris et al. 2021 ⁴⁷			*	*	*		*	*
Danino et al. 2024 ⁴⁸	*		*	*	NA	*	*	*
Glicksman et al. 2023 ²	*	*	*	*	*	ı	*	*
Glicksman et al. 2023 ³	*	*	*	*	*	ı	*	*
Greenbaum et al.	*	,	,	*	NA		*	*
Katsnelson et al. 2021 ⁵	*		*	*	NA	*	*	ı
Khoo et al. 2019 ⁵⁰	*	*	*	*	*	*	*	*
Lee et al. 2020 ²³		*		*	*		*	*
Lieffering et al. 2024 ⁷	*	*	*	*	*	*	*	ı
McCranie et al. 2024 ⁹	*	ı	*	*	NA	ı	*	*
McGuire et al. 2024 ¹⁰	*	*	ı	*	*	ı	*	*
Messa & Messa 2023 ¹¹	*		*	*	NA	1	*	ı
Metzinger et al. 2022 ¹²	*		*	*	NA	ı	*	
Miranda et al. 2024 ¹³		ı	1	*	NA		*	*
Miseré & van der Hulst	*	,	*	*	NA	*	*	ŗ
Micorá ot al 200114	*	*		*	*		*	*
Serena et al 2021	*			*	۸A		*	*
Singh et al. 2018 ⁵²	*		*	*	NA	*	*	ı
Spit et al. 2024 ¹⁹	*	ı	*	*	NA		*	*
Spit et al. 2022 ²⁰	*	*	*	*	*		*	*
Wee et al. 2021 ⁵³	*	ı	*	*	NA	ı	*	,
Wee et al. 2020 ²¹	*	,	*	*	NA		*	*
Woźniak-Roszkowska	*	,	*	*	NA	1	*	r
דו מו. בטבט דו אממת מו זו זו זו זו זו זו	*		*	*		*	*	
zhang et al. 2023	¢		¢	¢	NA	c	¢	
Abbreviation: NA = Not * Present. - Not present.	applicable.							

Checklist for Case Series was used for Alijotas-Reig et al., 2018 and Habib et al., 2022. Both studies^{44,45} were deemed low risk for bias and were included in this systematic review.

Characteristics of patients and breast implants

A total of 7045 patients with breast implants were included in this review. Of these, 3444 patients (49%) presented with the constellation of symptoms often grouped as BII. Among patients with documented implant types, 1939 patients (28%) had silicone implants, 900 patients (13%) had saline implants, 765 patients (11%) had textured implants, and 1804 patients 26% had smooth implants.

4423 patients (63%) had their implants explanted, and 2502 of those patients (57%) reported symptoms of BII prior to the procedure. Postexplantation, 1077 patients (43%) reported improvement in symptoms or resolution of complaints, with 241 patients (10%) reporting complete resolution of symptoms.

Regarding implant-specific complications, 1050 patients (15%) had ruptured implants, and 3104 patients (44%) reported capsular contracture, independent of experiencing symptoms of BII. In comparison, among patients with reported symptoms of BII (n = 3444), 167 patients (5%) reported implant rupture, and 936 (27%) reported capsular contracture.

Presenting symptoms and complaints

The most prevalent presenting patient complaints included: 2425 patients (34%) reported arthralgia and/or myalgia, 1477 patients (21%) reported cognitive dysfunction such as brain fog and/or loss of concentration, and 1685 patients (24%) reported fatigue and/or malaise. 1040 patients (15%) also reported local changes around the breast implants and/ or pain around the implants and/or underarms. Notably, psychological symptoms were only reported in 730 patients (10%) when presenting initially for symptoms of BII. A summary of presenting symptoms and complaints is shown in Figure 2.

Comorbid conditions

The most commonly reported comorbid conditions included tobacco smoking history in 1005 patients (14%), allergies in 506 patients (7%), established autoimmune diagnoses in 409 patients (6%), and established psychiatric diagnoses (mainly major depressive disorder and/or general anxiety disorder) in 316 patients (5%). A summary of comorbid conditions is presented in Figure 3.

Potentially associated conditions or risk factors

Univariable meta-regression revealed significant linear relationships between several factors and the percentage of patients reporting symptoms of BII. This included the percentage of patients with history of malignancy (3.46, CI: [0.65, 6.28] p = 0.0345), the percentage of patients who underwent explantation (0.7, CI: [0.32, 1.09] p < 0.001), and the percentage of patients with no residual symptoms postexplantation (0.3, CI: [0.06, 0.54], p = 0.0336). After excluding studies with fewer than 20 patients to eliminate any potential confounding influence to conduct a secondary sensitivity analysis, the relationship between explantation rates and the reporting of symptoms of BII remained significant (0.71, CI: [0.2, 1.22], p = 0.0129).

Spearman correlation tests confirmed these relationships, showing significant correlations between reporting of symptoms of BII and: history of malignancy (R = 0.6425, p = 0.018), symptom improvement/resolution postexplantation (R = 0.5670, p < 0.001), and complete symptom resolution postexplantation (R = 0.8828, p < 0.001). Notably, when excluding studies with fewer than 20 patients, the correlation between complete symptom resolution postexplantation and reporting of symptoms of BII remained strong (R = 0.9, p = 0.037).



Figure 2 Presenting Symptom Prevalence Across Systematic Review and Meta-Analysis. SICCA refers to the dryness of eyes and



Figure 3 Frequency of Comorbid Conditions Among Patients in the Systematic Review and Meta-Analysis.

Discussion

Key findings

Our key findings are the following:

- 1. The most common presenting symptoms for BII were arthralgia and/or myalgia, cognitive dysfunction and fatigue and/or malaise.
- The most common comorbid conditions were active or former smoking, allergic disorders, and established autoimmune diagnosis.
- 3. The most significant associated condition was a history of malignancy.
- 4. The proportion of patients that experienced symptom improvement or complete resolution after implant explantation was strongly correlated with the proportion of patients self-reporting symptoms of BII. This suggests potential validation of probable pre-explantation BII phenomena.

Patient self-selection

It is interesting to consider the role of patient self-selection regarding the BII phenomena. A recent retrospective cohort study was conducted over multiple consultations that found women with silicone breast implants had an increased odds of experiencing three or more distinct health symptoms after cosmetic surgery than before implantation and compared with women without silicone breast implants.⁵⁶ Women who undergo silicone implant augmentation have been reported to experience higher levels of anxiety. This pre-existing anxiety may influence the decision to undergo breast augmentation and increase the likelihood of somatization.^{13,56} This suggests an association between health symptoms such as BII and cosmetic augmentation with implants in women.^{13,56} Furthermore, since a high proportion of patients often self-report improvement in BII symptomatology after

explantation, it is important to consider shared decision making regarding management and treatment when patients present with any BII phenomena.¹³ Because of the large number and diversity of symptoms self-reported by patients, BII symptomology is most likely a complex interaction between biophysiology and psychology, as later discussed. Due to this unpredictability, it is difficult not just to accurately diagnose BII phenomena but also to identify patients who will benefit from surgical intervention.¹³ It is unclear what is required for patients to be considered for potential explantation and capsulectomy, but it might be useful to consider the presence of at least two of the top 10 BII symptoms: fatigue, arthralgia/myalgia, brain/memory fog, mood disturbances, neuropathic pain, hair loss, headaches, gastric symptoms/intolerances, rash, and vision disturbances, and at least two lower tier symptoms, such as palpitations, insomnia, tinnitus, and dyspnea, among others.¹

Bll and autoimmune disorders

Analysis revealed that 6% of patients with breast implants had pre-existing autoimmune disorders. While not the most prevalent comorbidity observed in this review, autoimmune conditions remained notable across included studies. An included retrospective analysis of 45 cases examining lateonset, noninfectious inflammatory, and/or autoimmune disorders related to bioimplants demonstrated that breast implants can trigger late-onset systemic autoimmune disorders meeting the autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA) diagnostic criteria. These initially present as localized inflammatory reactions that may evolve into systemic autoimmune disorders.⁴⁴ Of the 45 cases, 19 involved silicone breast implants, with all patients developing autoimmune disorders, including systemic sclerosis (10%) and Sjogren's syndrome (10%).⁴⁴

A case report described the detection of silicone implant incompatibility syndrome (SIIS) and highlighted an immune response from the body that could mimic malignancy and metastases.²⁸ Notably, SIIS presentation may be delayed, presenting years after removal of a ruptured implants.²⁸ Similarly, another case described multicentric reticulohistiocytosis with peculiar laryngeal involvement, potentially linked to implant-associated inflammatory syndrome.³¹ These cases, among others mentioned in the review, suggest the concurrent development of multiple inflammatory conditions that may be associated with prosthetic implant-induced immune responses.^{31,34–36,39,51}

One case report described a patient with a history of bilateral retro-pectoral silicone breast augmentation and a previous thoracic sympathectomy presenting 20 years later with a ruptured implant and a Baker 4 capsular contracture on the left breast.²⁹ After implant exchange, the patient developed silicone granulomas, which were discovered during investigation of progressive fatigue.²⁹ The granulomas resulted from silicone spillage into the thoracic cavity during the previous sympathectomy.²⁹ The literature postulates that aging implants may trigger macrophage activation, leading to further histiocytic reaction with the formation of siliconomas, even at distant sites.^{29,35} Another included retrospective study took this postulation further by stating that since BII and mast cell activation syndrome (MCAS) have similar symptom profiles in practice, and given the commonly observed natural history in MCAS of worsened mast cell activation upon exposure to novel antigens, many patients who are experiencing symptoms of BII may also suffer from MCAS.⁵¹

A North American study quantifying silicone particles in breast implant capsules found that five of 20 patients with silicone implants reported clinical symptoms, including chronic pain and skin necrosis.⁴⁸ However, the study concluded that since there was no silicone found in the saline implant capsules, silicone leakage was not the primary cause of BII symptoms.⁴⁸ Patients with saline breast implants are still susceptible to BII symptoms, regardless of the lack of silicone, due to the intricacies of BII phenomena and how the immune system may play a role in the manifestation of these symptoms.^{33,48}

Another case report described a 25-year-old patient presenting with asymptomatic silicone implant rupture and three major criteria for ASIA who improved after bilateral implant removal.³⁰ This case report suggests silicone may influence the immune system as an adjuvant, triggering possible autoimmune and connective tissue disease, in genetically predisposed patients.^{30,39} The hypothesized etiopathogenesis of BII, under the ASIA umbrella, involves a multifactorial interplay between environmental factors, genetic disposition, and the immune system.

BII and mental health

Five percent of the patients included in this systematic review had an established psychiatric diagnosis, mostly major depressive disorder and/or general anxiety disorder. This does not support the view that BII is related to preexisting psychologic conditions; however, there may be some interplay between a disposition toward or an established psychiatric diagnosis and the manifestation of BII symptoms among patients with breast implants. A UK study reported mood disturbances (36%), primarily depression and anxiety, as one of the 10 most frequently self-reported symptoms among patients presenting with BII.¹³

A retrospective review of patients undergoing breast implant removal related to BII symptomology demonstrated that although 45% of the 47 total patients had a documented history of psychiatric illness, psychiatric illness had no significant impact on the outcomes of the BREAST-Q survey for symptom improvement after implant removal.¹ However, the study then stated that since the relationship between cause and effect in the development of BII is complex, it may be possible that there is a bidirectional relationship between psychiatric illness and BII. Patients with breast implants struggle with the physical symptoms of Bll and therefore, this discomfort may contribute to the development of mental and emotional distress.¹ Notably, physical well-being was the only domain with consistently high scores postremoval, suggesting patients might not fully process their satisfaction with breast appearance, body image, physical sensation, or sexual confidence-potentially contributing to ongoing psychological distress.

Another included study of 140 patients undergoing explantation of their breast implants due to BII symptomology found that 15.7% of patients chronically used psychoactive medications, such as antidepressants and benzodiazepines.²⁵ The study guestioned the rapid achievement of the stabilization of symptoms (within 30 days postoperatively) and proposed psychological factors might influence why only certain individuals report complete symptom remission.²⁵ Moreover, one study demonstrated that at baseline, the BII cohort of patients reported significantly higher levels of anxiety than both control groups.² Interestingly, after explantation, the BII cohort initially reported reduced levels of anxiety, which was not sustained.² The authors suggested that neuroticism might be associated with increased symptom reporting, noting that cosmetic surgery patients often exhibit higher neurotic tendencies and may hold strong beliefs about implant-related illness.²

The correlation between psychiatric diagnoses and BII self-reporting was further evidenced in a study in which all 29 patients that reported BII had high rates of psychological comorbidities.¹⁵ Women with silicone breast implants and BII reported significantly lower quality of life than women without implants,¹⁵ suggesting potential selection bias toward women with the most severe complaints or the most complex history.¹⁵ An included study of transgender women found that although some patients reported BII symptomology at one point after breast augmentation, the symptoms of gender dysphoria outweighed any association of their implants with BII, and thus, none of the participants elected to have their implants removed,⁹ highlighting potential psychological components in reporting of symptoms associated with BII.

Similarly, an included retrospective review of 248 patients that presented with BII symptomology and underwent implant removal demonstrated that 32% of the patients had a known medical history of anxiety, 15% with a history of depression, and 4% with a history of panic attacks.⁵ Of 46 patients that addressed specific symptoms postoperatively, 44 (96%) reported symptom reduction after surgery.⁵ This high improvement rate among patients with psychiatric diagnoses suggests a potential relationship between mental health and BII symptomology manifestation. One included study found that patients with psychiatric illness showed a strong propensity for improvement after implant removal (25.6%),¹⁸ with another case report stating that the patient reported a reduction in chronic anxiety postexplantation.⁴⁰ Overall, this comorbid condition cannot be excluded from the interplay of the environmental and genetic factors that can manifest as BII symptomology, as evident from the included studies.

BII and malignancy

Among the included studies, 3% of patients with breast implants had a history of malignancy, predominantly breast cancer. There is a significant relationship between a history of malignancy and the reporting of BII (R = 0.6425, p = 0.018; 3.46, CI: (0.65, 6.28) p = 0.0345). This relationship aligns with clinical patterns, as silicone implant reconstruction is the most common form of breast reconstruction following mastectomy.

A study conducted previously showed that all 398 participants who presented to the clinic had unexplained systemic symptoms, of which 103 participants had a history of receiving breast implants following a mastectomy, after breast cancer treatment, or because of a genetic predisposition for breast cancer, such as *BRCA* gene mutation.²⁰ Another included study reported that there were 259 patients with high and moderate suspicion for BII, out of the total 353 patients.¹⁹ In this study, 50 (14.2%) women received breast implants postmastectomy following breast cancer, and 26 women (7.4%) had reconstruction after bilateral preventive mastectomy in women with a *BRCA1*, *BRCA2*, or *CHEK2* mutation or another form of hereditary breast cancer.¹⁹

Similarly, most patients whom reported symptoms of BII (90%) in another included study reported having been diagnosed with a medical condition, whereas only 27% without BII had a diagnosed medical condition.¹⁶This study further corroborates that patients with a history of malignancy are more likely to report BII because it found that patients with BII were significantly more likely to have a history of breast cancer or other cancers than women without BII (p = 0.05; p = 0.045).¹⁶

The association between malignancy history and BII reporting may stem from multiple factors: the higher proportion of cancer survivors receiving implants, potential immune system alterations after cancer treatment, and possibly increased health vigilance or illness anxiety among cancer survivors.

BII and clinical decision making

The analysis revealed that 4423 patients (63%) had their implants explanted, often due to experiencing symptoms associated with BII. A significant relationship emerged between explantation rates and reporting of BII symptomology, as well as between postexplantation symptom improvement/resolution and reporting of BII symptomology.

An included retrospective cohort study reported cosmetic dissatisfaction, capsular contracture, and pain symptoms potentially falling within the BII spectrum as primary motivations for explantation.¹⁷ An included study demonstrated that patients who experienced symptoms associated with BII had a statistically significant improvement in their symptoms after explantation and that this improvement persisted for at

least 6 months postoperatively.³ This improvement in self-reported systemic symptoms was seen regardless of the type of capsulectomy performed.³ Similarly, another included study demonstrated a significant improvement in quality of life, including psychological well-being (p <.005), after breast explantation and capsulectomy.¹¹ With respect to experiencing BII symptoms, 59 patients (88.1%) noted reduced pain, myalgias/arthralgias, and fatigue after their procedures.¹¹

An investigation of specific BII manifestations revealed that among 47 patients with hearing impairment, 27 (57.4%) experienced symptom improvement or resolution postexplantation (Z = -4.863; p < 0.0001).⁴⁹ A case series of three patients who were believed to be suffering from BII symptomology documented complete symptom resolution following en-bloc resection.⁴⁵ The authors proposed that symptom improvement might relate to removing a source of systemic inflammation, potentially addressing either new-onset conditions or exacerbating an underlying systemic illness.⁴⁵ Other included case reports support this hypothesis, suggesting breast implants may trigger a foreign body reaction that results in granulomatous inflammation, microbial biofilm formation, and a chronic inflammatory response.^{23,32,37}

Additionally, a prospective study that followed 50 patients for BII symptomology after their explantation demonstrated that 84% of patients reported partial or complete resolution of BII symptoms postoperatively.²³ This study, like others included in this review, further corroborates the notion that removing the implants most likely removes the source of inflammation by identifying microbiological and histological abnormalities in the breast implants of the patients.^{23,37} A cross-sectional study of 182 respondents found that among the 40% who underwent explantation, 97% reported symptom relief (23% complete, 74% partial resolution), with significant improvement in all but one reported symptom.⁸

Multiple included studies consistently demonstrated symptomatic improvement after explantation.^{10,24,53,54} While the precise mechanism of the role of breast implants in the BII phenomenon remains unclear, clinical evidence supports explantation as an effective intervention for symptom resolution in affected patients.

Limitations and strengths

The meta-analysis has several methodological limitations. The analysis relied on study-level summary statistics rather than individual-level data. Missing values were also common because not all the studies collected the same variables of interest. There was vast heterogeneity across the included studies regarding study design and patient populations. The distribution of the percentages of patients experiencing BII symptomology showed significant skew, influenced by numerous case reports and small studies reporting 100% BII incidence. Consequently, linear relationships between the reporting of BII-related symptoms and specific comorbidities may not be accurately represented by weighted linear regression coefficients. These models served primarily to identify potential associations rather than quantify them.

The main strength of this systematic review and metaanalysis is the collation of data from the literature, which allows medical providers to have a vast amount of information in one place about how presenting symptoms of BII can manifest and what comorbid conditions patients with BII may have. Additionally, it establishes a foundation for quantifying BII risk factors and developing diagnostic guidelines in the future.

Future research

Future studies should be large-scale and specific, quantifying the risk of developing BII-related symptoms among individual patients with specific comorbid conditions because the identified associations could be potential risk factors. This review demonstrates that although some comorbid conditions or presenting symptoms may be more prevalent than others, each condition or symptom does not occur in isolation, and thus, future large-scale studies need to consider how diverse the presentation of BII can be. The variability of symptoms, lack of clear diagnostic criteria, and absence of long-term safety and efficacy data challenges our current knowledge, but it should not overshadow the progress of research for the diagnosis and treatment of BII.

Conclusion

Among the patients that presented with one or more symptoms of BII, 51% had other explainable diagnoses or etiologies for their symptoms that precluded the diagnosis of BII. These findings highlight the need for more research into BII etiology, diagnosis, and management and improved patient education and follow-up protocols.

Ethical approval

Not required.

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Conflict of Interest

None.

Appendix A. Supporting information

Supplemental data associated with this article can be found in the online version at doi:10.1016/j.bjps.2025.03.026.

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